

REMARKS/ARGUMENTS

Claims 1, 3, 4 and 5 have been amended. Claim 2 has been canceled. The amendments concern the replacement of "a macrolide T-cell immunomodulator" by "pimecrolimus" in new claims 1, 3 and 4. The amendment is based on the description, see e.g. p.2, 2nd paragraph and claim 2 as filed is incorporated into claim 1. No new matter has been introduced.

Rejection under 35 U.S.C. §112

Claim 3 is rejected under 35 U.S.C. §112 first paragraph and second paragraph. Applicant's amendments to the claims should obviate these rejections. In view of the amendments Applicants respectfully request that the Examiner reconsider and withdraw the 35 U.S.C. §112 first paragraph and second paragraph rejections concerning claim 3.

Rejection under 35 U.S.C. §102/103

Claims 1, 3 and 4 are rejected under 35 U.S.C. §102/103 over Van Etten et al., WO98/18468, Nghiem P. et al., Paul C. et al., Baumann et al., Van de Kerkhof et al., and Koo et al. Applicants respectfully traverse.

Van Etten describes that the vitamin D analog 1,25(OH)₂D₃ has synergistic immunomodulatory effects when used together with cyclosporine, rapamycin and FK506. The aim of this study is the investigation whether this synergism could be observed also with the specifically mentioned other immunosuppressants, namely mycophenolate mofetil, leflunomide and the methylxanthine A802715, or with analogs of 1,25(OH)₂D₃ (see e.g. abstract). Differences in synergism for the various combinations have been noted and are depending on several factors, such as e.g. the kind of immunomodulator used, the kind of vitamin D analog used, dosages used etc. Pimecrolimus is not even mentioned in this document. A person skilled in the art would not have motivation to provide a composition of the present invention when reading this document, especially in view of the high unpredictability of a possible synergism and the multi-factorial influences.

WO98/18468 describes a combination of rapamycin and calcitriol (=1,25-dihydroxy-cholecalciferol), which can be used in the treatment of various autoimmune and inflammatory diseases.

Nowhere in this document any other active ingredient besides rapamycin is mentioned, nor is there any suggestion for a person skilled in the art to come up with a composition comprising pimecrolimus in association with calcipotriol or tacalcitol.

Nghiem P. et al. is a more general article about the mechanism of calcineurin inhibitors for treating atopic dermatitis.

Nothing in this articles describes or suggests a combination of pimecrolimus with a substance of present claim 1 as on file.

Paul C. et al. is a review article, which gives an overview of ascomycins and their use for treating inflammatory skin diseases. Again, nothing in this documents describes or suggest a combination of pimecrolimus as of claim 1 on file.

Baumann et al. This patent of Novartis deals with new ascomycin compounds and includes pimecrolimus as such. No combination as of claim 1 on file is described or suggested.

Van de Kerkhof et al. describes the effects of vitamin D3 analogues when used for topical treatment and i.e. that tacalcitol ointment is an effective long-term treatment in patients with chronic plaque psoriasis. No combination as of claim 1 on file is described or suggested.

Koo et al. deals with a general method for administering a dermatological agent and hereby used the occlusion of such an agnet in a hydrogel patch. In a long list of possible agents pimecrolimus and vitamin D derivatives are mentioned besides many other possible substances. No combination of any of these substances is described or suggested.

We submit that the claims are novel in view of the current amendments and there is no suggestion in any one of the cited prior art documents, neither alone or in combination of these documents, to provide a pimecrolimus composition of the present invention.

In view of the remarks and amendments, further and favorable consideration of the present application and the allowance of all pending claims are respectfully requested. The Examiner is also invited to contact the undersigned should the Examiner believe that such contact would expedite prosecution of the present application.

Respectfully submitted,

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